REMARKS:

Claims 1-6 are in the case and presented for consideration.

The drawings have been objected to because the labels "C" and "0" in Fig. 7 were overlapping. Applicant thanks the examiner for pointing this out. A replacement drawing of Fig. 7 is enclosed herewith which corrects the overlap by separating the "C" and "0" labels.

The sequence listing has been objected to because the peptide sequences are not found in the specification. Accordingly, the VIP peptide sequence has been added to the specification as Fig. 10. Reference is made to Fig. 10 in amended paragraph 19 on page 6 of the specification, as well as assigned identifier SEQ. ID. NO: 1 in the Sequence Listing.

The examiner has also objected to the failure to list the sequences for the nucleic acid probes TNFα and IL-6. The sequences have therefore been listed in the accompanying Sequence Listing using the assigned identifiers SEQ ID NO: 2 and SEQ ID NO: 3 respectively. Appropriate reference is made to the assigned identifiers SEQ ID NO: 2 and SEQ ID NO: 3 respectively in the sequence listing in amended paragraph 62 on pages 16-17.

The examiner has also objected to the failure to list the sequences for the peptides [K 15 ,R 16 ,L 27]VIP [1–7]-GRF [8–27] and Ro 25–1553 Ac-[Glu 8 ,Lys 12 ,Nle 17 ,Ala 19 ,Asp 25 , Leu 26 ,Lys 27,28 ,Gly 29,30 ,Thr 31]-VIP cyclo [21–25] discussed in paragraph 74 on page 20. The sequences have therefore been listed in the accompanying Sequence Listing as assigned identifiers SEQ ID NO: 4 and SEQ ID NO: 5 respectively. The sequence listings are also shown in Figs. 11 and 12 respectively. Appropriate reference is made to the sequence listing and drawings in amended paragraph 74 on page 20 of the specification.

The specification was objected to because the cross-reference to related applications mentioned application no. 09/446,352 that has matured into a U.S. Patent 6,429,188. Accordingly, the application number has been replaced with the U.S. Patent number.

The specification was also objected to because Fig. 8 describes 4 different figures. Accordingly, the description of Fig. 8 has now been separated into descriptions for Figs. 8A, 8B, 8C, and 8D.

Claim 1 was objected to for various informalities including abbreviation of the term VPAC1 and grammar. Accordingly, claim 1 has been rewritten only to overcome the objection to these informalities under 35 U.S.C. §112.

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Fishbein et al. In particular, the examiner states that Fishbein teaches pseudopeptide VPAC1 receptor agonists placed in an HPLC loading buffer.

Applicant respectfully submits that Fishbein fails to teach at least one element or limitation recited in independent claim 1. Claim 1 recites:

> A pharmaceutical composition for the treatment and/or prevention of septic shock, comprising vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist with a pharmaceutically acceptable carrier.

Fishbein fails to teach a pharmaceutical composition comprising a "pharmaceutically acceptable carrier." Paragraph 53 of the specification clearly states:

> Besides the pharmaceutically acceptable carrier, the compositions of the invention can also comprise minor amounts of additives, such as stabilizers, excipients, buffers and preservatives.

Therefore, buffers have been explicitly excluded from the definition of the term "pharmaceutically acceptable carrier" in the specification. Since HPLC loading buffer is a buffer as described in the specification, it is excluded from the definition of the term "pharmaceutically acceptable carrier." Thus, Fishbein fails to teach a pharmaceutically acceptable carrier as recited in independent claim 1.

Applicants further note that Fishbein only teaches purification of VIP analogues on a column by elution with acetic acid, followed by chromatography on a silica column by elution with linear gradients of acetonitrile in 0.1% trifluoroacetic acid. Chromatography is a purification step. Fishbein does not teach HPLC loading buffer for administration of an active ingredient into a human body. Fishbein fails to teach or suggest any pharmaceutically acceptable carrier for administering an active agent into a human body. Fishbein does not teach a pharmaceutically acceptable carrier that does not interfere with the effectiveness of biological activity of the active ingredient and is not toxic to the host to which it is administered. If the examiner believes through personal knowledge that such a loading buffer would not interfere with the effectiveness of biological activity of the active ingredient and would not be toxic to the host to which it is administered, the examiner is invited to provide an affidavit supporting his contention pursuant to 37 C.F.R. §1.104(d)(2).

Claim 1 has further been rejected under 35 U.S.C. §102(a) as being anticipated by Xia et al. The examiner again defines a chromatography loading buffer as a pharmaceutically acceptable carrier. Therefore, applicant respectfully submits that Xia et al. fails to teach a pharmaceutically acceptable carrier as recited in independent claim 1 for the same reasons as stated above for Fishbein.

Thus, all of the claims are believed to be novel and nonobvious.

The application and claims are believed to be in condition for allowance, and favorable action is respectfully requested. No new matter has been added.

If any issues remain which may be resolved by telephonic communication, the Examiner is respectfully invited to contact the undersigned at the number below, if such will advance the application to allowance.

Respectfully submitted,

Peter C. Michalos
Reg. No. 28,643
Attorney for Applicants
Phone: (845) 359-7700

Dated: March 17, 2004

NOTARO & MICHALOS P.C.
100 Dutch Hill Road
Suite 110
Orangeburg, New York 10962-2100

Customer No. 21706

PCM:YG:al
Encs.